REMARKS

Claims 1-27 are pending. Claims 1, 12, and 23 are in independent form.

In the action mailed December 16, 2005, claim 1 was rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,308,094 to Shusterman et al. (hereinafter "Shusterman") and under 35 U.S.C. § 103(a) as obvious over Shusterman and U.S. Patent No. 5,987,352 to Klein et al. (hereinafter "Klein").

Claim 1 relates to a method that includes determining a beat-to-beat variability in cardiac electrical activity, determining a relevance of the variability to one of atrial fibrillation and atrial flutter using a non-linear statistics, and identifying one of an atrial fibrillation event and an atrial flutter event based on the determined relevance. The event is a period in time when the information content of the cardiac electrical activity is of increased relevance to one of atrial fibrillation and atrial flutter.

The rejections of claim 1 rest on the assertion that Shusterman describes using a non-linear statistics to determine a relevance of a beat-to-beat variability to one of atrial fibrillation and atrial flutter. Applicant respectfully disagrees with this assertion.

Rather than using a non-linear statistics, Shusterman uses the Karhunen-Loeve Transformation (KLT) for the detection of linear and non-linear changes in a beat-to-beat heart rate time series. *See, e.g., Shusterman*, col. 5, line 33-37. Submitted herewith is a copy of pages 240-241 of "Vector Quantization and Signal Compression" by Allen Gersho, Robert M. Gray, which identifies that the Karhunen-Loeve transformation is a linear transformation.

Shusterman's statistics, therefore, are understood to be linear even though the detected changes in a beat-to-beat heart rate are themselves non-linear.

Moreover, Shusterman himself is understood to identify that his methods are linear and teaches that non-linear methods are ineffective for identifying a pattern, an onset time, and a magnitude of changes in the complexity of RR-series. *See Shusterman*, col. 7, line 53-56. As a result of this ineffectiveness, Shusterman indicates that the practical value of non-linear methods for the short-term prediction of life-threatening cardiac arrhythmias is diminished. *See Shusterman*, col. 7, line 56-58. Such teachings away from the claimed subject matter are a strong disincentive to modify Shusterman to arrive at the claimed subject matter. Hence, any obviousness rejection that relies on Shusterman would, as a general rule, be improper.

Since Shusterman neither describes nor suggest using a non-linear statistics to determine a relevance of a beat-to-beat variability to one of atrial fibrillation and atrial flutter, claim 1 is not anticipated by Shusterman and applicant requests that the rejection be withdrawn.

Klein does nothing to remedy this deficiency in Shusterman. Rather than providing details as to how a relevance of a beat-to-beat variability to one of atrial fibrillation and atrial flutter is to be determined, Klein discusses only an unspecific event trigger.

Since elements and/or limitations recited in claim 1 are neither described nor suggested by Shusterman and Klein, a *prima facie* case of obviousness has not been established. Applicant therefore requests that the rejections of claim 1 and the claims dependent therefrom be withdrawn.

Claim 12 was rejected under 35 U.S.C. § 102(b) as anticipated by Shusterman. Claim 12 relates to a method that includes collecting information describing the variability in heart rate over a series of beats, designating variability at a lower end of physiological values as being substantially irrelevant to atrial fibrillation, designating variability in a midrange of physiological values as being positively indicative of atrial fibrillation, designating variability in an upper range of physiological values as being negatively indicative of atrial fibrillation, and determining a relevance of the variability described in the collection of information to atrial fibrillation.

The rejection of claim 12 does not set forth any basis on which the rejection is founded. Since 37 C.F.R. § 1.104(2) requires that the reasons for any adverse action be stated in an Office action, the rejection is facially deficient and Applicant requests that it be withdrawn. Further, Applicant respectfully requests that the reasons for the rejection of any claim, including claim 12, be set forth so that Applicant may judge the propriety of continuing prosecution.

Indeed, the only statement relevant to the rejection of claim 12 appears to be set forth in the rejection of claims 24 and 25. In particular, the rejection of claims 24 and 25 baldly asserts that

> "it is inherent that lower end of physiological values are largely irrelevant to atrial fibrillation and upper range of physiological values negatively indicate atrial fibrillation. Schusterman et al teach arrythmias may vary in severity from those that are mild and require no treatment to those that are catastrophic and life threatening."

To begin with, there is no indication that Schusterman knew of any relationship between physiological range of variability in heart rate and atrial fibrillation. Regardless of any inherency in the relationship between physiological range of variability in heart rate and atrial fibrillation,

one must actually know of the relationship in order to determine the relevance of the variability to atrial fibrillation, as recited in claim 12.

Further, even if *arguendo* Schusterman knew of such a relationship, there is no indication that Schusterman relied upon this relationship to determine a relevance to atrial fibrillation. Indeed, Schusterman is understood to identify impending cardiac arrhythmias by identifying simultaneous changes in Karhunen-Loeve Transformation (KLT) coefficients that are indicative of "pronounced and complex changes in the RR-series." *See Schusterman*, col. 6, line 36-41. Indeed, when Schusterman discusses predicting the onset of atrial fibrillation, he describes that the KLT coefficients simply exceed certain thresholds defined using the standard deviations of the coefficients. *See Schusterman*, col. 9, line 23-53. There is no reason to believe that Schusterman's "pronounced" changes in the RR-series are outside the lower end of physiological values (and hence not substantially irrelevant to atrial fibrillation) or outside the upper range of physiological values (and hence not negatively indicative of atrial fibrillation).

Accordingly, claims 12, 24, 25, and the claims dependent therefrom are not anticipated by Schusterman. Applicant requests that these rejections be withdrawn.

Claim 23 was rejected under 35 U.S.C. § 102(b) as anticipated by Shusterman. Claim 23 relates to a method that includes comparing recent R to R intervals with preceding R to R intervals to yield a collection of comparisons, weighting the comparisons according to a likelihood that the comparisons are relevant to atrial fibrillation, and determining the average relevance of the collection to atrial fibrillation. The weighting includes identifying a beat of a

collection of recent beats as a ventricular beat and assigning a preset value to weight the beat in the collection, the preset value being negatively indicative of atrial fibrillation;.

Schusterman neither describes nor suggests identifying a first beat as a ventricular beat, and assigning a preset value that is negatively indicative of atrial fibrillation to weight the first beat. Indeed, Schusterman does not make any mention of ventricular beats at all, much less assigning a preset value that is negatively indicative of atrial fibrillation to a ventricular beat.

Accordingly, claim 23 and the claims dependent therefrom are not anticipated by Schusterman. Applicant requests that these rejections be withdrawn.

No fees are believed due at this time. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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John F. Conroy
Reg. No. 45,485

Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

JFC/jhg
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